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DATE MAILED: 11/01/2004

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/347,311	07/02/1999	GEERT PLAETINCK	B0192/7010	3674
75	90 11/01/2004		EXAM	INER
JOHN R VAN AMSTERDAM			WOITACH, JOSEPH T	
C/O WOLF GREENFIELD & SACKS P C FEDERAL RESERVE PLAZA			ART UNIT	PAPER NUMBER
	600 ATLANTIC AVENUE			*
BOSTON, MA 022102211			DATEMAN ED 11/01/2004	

Please find below and/or attached an Office communication concerning this application or proceeding.

· ·	Application No.	Applicant(s)				
	09/347,311	PLAETINCK ET AL.				
Office Action Summary	Examiner	Art Unit				
	Joseph T. Woitach	1632				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1) Responsive to communication(s) filed on 10/4/04.						
2a)⊠ This action is <b>FINAL</b> . 2b)□ Thi	s action is non-final.					
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims						
4) Claim(s) 1-15,17-24,38-45,47  and 92 is/are pending in the application.  4a) Of the above claim(s) 22 is/are withdrawn from consideration.  5) Claim(s) is/are allowed.  6) Claim(s) 1-15,17-21,23,24,38-45,47  and 92 is/are rejected.  7) Claim(s) is/are objected to.  8) Claim(s) are subject to restriction and/or election requirement.						
Application Papers						
9) The specification is objected to by the Examiner.						
10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) All b) Some * c) None of:  1. Certified copies of the priority documents have been received.  2. Certified copies of the priority documents have been received in Application No  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.						
Attachment(s)						
<ol> <li>Notice of References Cited (PTO-892)</li> <li>Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08 Paper No(s)/Mail Date</li> </ol>	4) Interview Summary Paper No(s)/Mail Da  5) Notice of Informal P  6) Other:					

### **DETAILED ACTION**

This application, filed July 2, 1999, claims benefit of foreign applications: GB 9814536.0, filed July 3, 1998, and GB 9827152.1, filed December 9, 1998, both filed in Great Britain.

Applicant's amendment filed October 4, 2004, has been received and entered. Claims 1, 3, 12-14,20, 21, 38, 41, and 42 have been amended. Claims 16, 23-37, 46, 48-91 have been canceled. Claims 1-15, 17-22, 38-45, 47 and 92 are pending.

It is noted that claim 22 has the claim identifier of (Original), however this should have the identifier of (Withdrawn). This should be corrected in any subsequent amendment.

### Election/Restriction

Claims 1-15, 17-22, 38-45, 47 and 92 are pending. Claim 22 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 17. Claims 1-15, 17-21, 23, 24, 38-45, 47, 48 and 92 are currently under examination.

## Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1-15, 17-21, 23, 24, 38-45, 47, 48 and 92 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn.

The amendment to the claims have addressed the basis of each of the specific rejections.

### Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-15, 17-21, 23, 24, 38-45, 47, and 92 stand rejected under 35 U.S.C. 102(e) as being anticipated by Fire *et al.* (US Patent 6,506,559 B1).

Applicant argues that the filing date of the foreign applications indicated in the priority claim are prior to the filing date of '559. See Applicant's amendment, page 8. Applicant's arguments have been fully considered, but not found persuasive.

It is noted that the filing date of the '559 patent is December 18, 1998, however it claims priority to provisional application 60/068,562, filed December 23, 1997. Applicant's arguments are not found persuasive because the Fire *et al.* patent has an earlier effective filing date than the instant application, and qualifies as a 102(e) type reference.

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Applicant does not contest the substance of the teachings of Fire *et al.* provided in the basis of the rejection. As noted previously, Fire *et al.* teach that dsRNA can be used in *C. elegans* to inhibit the expression of endogenous gene. The dsRNA can be administered to C. elegans in a variety of ways, including through the ingestion of a bacteria that expresses and provides for dsRNA (column 5, lines 9-11). Fire *et al.* provide a variety of methods in which this system can be used to inhibit gene expression in C elegans including determining the importance of any genes expression (column 5, lines 34-37). In detail Fire *et al.* provide methods for making DNA libraries in vectors, where the resulting vectors are capable of generating dsRNA from the inserted DNA (starting in column 12, line 16). Fire *et al.* teach that the vectors that express dsRNA can be used to determine any genes function in a high throughput manner. Thus, for the reasons above and of record the methods and materials taught by Fire *et al.* anticipate the instantly claimed invention, and the rejection is maintained.

### **Double Patenting**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 1-15, 17-21, 23, 24, 38-45, 47, **49** and 92 <u>stand</u> provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-41 of copending Application No. 10/057,108.

Applicants note that the rejection is provisional, and make no response at this time. See Applicant's amendment, pages 8-9. Applicant's response is noted, however the claimed subject matter has not been found allowable, and application 10/057,108 is still pending. Review of 10/057,108 indicates that the claims have been amended, however the subject matter claimed is not patentably distinct from that instantly claimed. As stated in the previous office action, although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed methods are both drawn to administering dsRNA to *C. elegans* through the use of a micro-organism. Each require the use of vectors that express a DNA and result in a dsRNA. Each encompass the use of a DNA library and for providing the micro-organism comprising the vector to *C. elegans* in order to determine the phenotypic affect of silencing the expression of a gene.

As noted by Applicant, this is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

#### Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (571) 272-0734.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach

Joe Worter